IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ABBOTT GMBH & CO., KG, ABBOTT BIORESEARCH CENTER, INC., ABBOTT BIOTECHNOLOGY, LTD. Plaintiffs, v. CENTOCOR ORTHO BIOTECH, INC., CENTOCOR BIOLOGICS, LLC. Defendants.	**C.A. No. 4:09-CV-11340 (FDS)** **JURY TRIAL DEMANDED**
CENTOCOR ORTHO BIOTECH, INC. Plaintiff, v. ABBOTT GMBH & CO., KG, Defendant.	**C.A. No. 4:10-CV-40003 (FDS)**

ABBOTT'S RESPONSE TO CENTOCOR'S BENCH MEMO REGARDING THE WRITTEN DESCRIPTION REQUIREMENT

Abbott responds as follows to the bench memorandum submitted by Centocor on the issue of the written description requirement.

I. The "Representative Species" Test

The parties agree that the relevant test for determining compliance with the written description requirement is whether Abbott's asserted patents disclose:

> ***either*** [1] a representative number of species falling within the scope of the [claimed] genus ***or*** [2] structural features common to the members of the genus so that one of skill in the art can "visualize or recognize" the members of the genus.

Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (emphases added) (quoting *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997)).

Although clearly setting forth two distinct tests ("either/or"), neither *Eli Lilly*, which first described the test, nor *Ariad*, which confirmed its validity, further defined what it means to be "representative." In both cases, as in many others, the number of disclosed species was zero, so there was no need to address the issue. *See, e.g., Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1344 (Fed. Cir. 2011), *cert. denied*, 132 S. Ct. 1542 (2012) (no written description because Centocor's "specification does not describe a single antibody that satisfies the claim limitations").

After *Eli Lilly* was decided, the PTO promulgated regulations for evaluating biotechnology and chemical inventions under the written description test. Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112, ¶ 1, "Written Description Requirement," 66 Fed. Reg. 1099-01 (Jan. 5, 2001) ("PTO Guidelines"). The PTO Guidelines expanded on *Eli Lilly* by establishing that the two tests set forth in *Eli Lilly* could also be

combined to satisfy the written description test. Citing the *Eli Lilly* case, the PTO Guidelines stated:

> The written description requirement for a claimed genus may be satisfied through sufficient description of [1] a representative number of species ... by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties,[1] [2] by functional characteristics coupled with a known or disclosed correlation between function and structure,[2] or [3] by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.
>
> * * *
>
> Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.

PTO Guidelines, 66 Fed. Reg. at 1106. The guidelines are quoted with approval by the Federal Circuit in its decision in *Carnegie Mellon University v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1124 (Fed. Cir. 2008). The PTO Guidelines and *Carnegie Mellon* show that the "representative species" test and the "common structural features" test are two separate ways to show that the written description requirement is met. They also show that written description can be shown

[1] This corresponds to the Federal Circuit's the representative species test – i.e., each representative species must be disclosed by sufficient identifying characteristics. Here, Abbott has provided the exact amino acid sequence for each representative species disclosed in the patent and thus has adequately described each representative species. Taken together, the disclosure of these representative species encompasses the variation of the salient features within the claimed genus, and thus satisfies the written description requirement.

[2] This corresponds to the Federal Circuit's structural features test, which is not at issue here.

"by a combination of such identifying characteristics." PTO Guidelines, 66 Fed. Reg. at 1106. What they do *not* say is that the only way to satisfy the written description test is to disclose all the structural variations within a claimed genus. *Id.* To the contrary, "applicants are not required to disclose every species encompassed by their claims even in an unpredictable art." *Eli Lilly*, 119 F.3d at 1569.

II. The *Carnegie Mellon* Case

In *Carnegie Mellon*, the claims at issue were "directed to recombinant plasmids that contain gene coding regions for the expression of DNA polymerase I ***from any bacterial source***." 541 F.3d at 1119 (emphasis added). The claim itself identified the source from which the claimed composition was derived – *i.e.*, "from any bacterial source." The Federal Circuit held that the patent failed the representative species test for the written description requirement because "the polA gene varied among the numerous bacterial species" and, in the patent, there was an "absence of any polA gene sequence for any bacteria other than E. coli." *Id.* at 1126. The court applied the representative species test by reference to the "bacterial sources" of the genes because the patent claims themselves identified "bacterial sources" as a relevant aspect of the claimed genus. *Id.* The issue was therefore whether a gene from one bacterial source could be representative of a gene derived from "potentially millions" of other bacterial sources. *Id.*

In contrast to the claims at issue in *Carnegie Mellon*, Abbott's asserted patent claims do not define the species of the claims by reference to the "source" of the antibody. Centocor's "lineage" argument, among others, fails for this reason. Here, as with almost every issue of patent law, the question of whether there is a sufficient number of representative species must

start with what is ***claimed.***[3] *Regents of the Univ. of California v. Dako North America, Inc.*, No. 05-3955, 2009 WL 1083446, at *10 (N.D. Cal. Apr. 22, 2009) ("Plaintiffs are not required to describe a high number of species of the genus method because the '841 patent, and the prior art cited therein, describes little variation within ***the salient characteristics*** of that genus." (emphasis added)); *see also Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005) ("Precedent illustrates that the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations ***appropriate to the subject matter***." (emphasis added)).

III. The Test Applied In This Case

Centocor seeks to focus exclusively on structural variety within the claimed genus to determine whether Abbott's disclosed species are "representative." Centocor's case is built around the proposition that Abbott purportedly fails to describe antibodies that are structurally similar to Stelara. That argument inherently collapses the two tests. *Eli Lilly* formulates two different tests and teaches that an invention can be claimed functionally and generically without (1) describing all the covered species and (2) even if there are no structural features common to the genus. *Eli Lilly*, 119 F.3d at 1569. If that is so, then an alleged showing that one species (Stelara) is structurally different from one of the disclosed species (J695) has little or no relevance to whether the complete set of disclosed antibody species are "representative" of the entire claimed genus. Thus, at best, Centocor has argued only that the asserted claims do not

[3] For example, antibodies within the claimed genus might vary by molecular weight. But molecular weight has nothing to do with the claimed invention or its purpose. Accordingly, variation with respect to that feature would not be relevant to compliance with the written description requirement.

meet the "structural similarity" test for written description. Centocor has failed to provide any legally sufficient evidence to show that Abbott's claims do not meet the separate representative species test.

The central issue for the representative species test in this case is not the alleged structural differences between Stelara and J695, but whether the variation among the disclosed antibody species is representative of the variation in the genus ***as claimed***. To the extent that the amino acid sequences are relevant at all, as explained by Dr. Wilson and as admitted by virtually all the witnesses, the portions of the sequences that are relevant to what is claimed are the complementarity determining regions ("CDRs") and, in particular, the CDR3 region. ***It is this region that is responsible for the binding characteristics of the antibody and hence its neutralization and affinity characteristics – the key distinguishing features of the claims***.

Moreover, all the structural differences that Centocor identifies between Stelara and J695 have nothing to do with the genus ***as claimed***. Centocor's argument focuses on differences in amino acid sequence outside the CDR regions (*e.g.*, Dr. Eck's chart comparing the amino acid sequences of the entire variable region of Stelara and J695) or the "lineage" of the disclosed antibodies (*e.g.*, Dr. Siegel's lineage argument). None of these structural features are claimed in any of Abbott's five asserted claims, and thus are not relevant to whether the disclosed species are representative of each claimed genus.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that, on September 20, 2012, this document (filed through the ECF system) will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Arthur W. Coviello